

**K954413 KELOCOTE**Nov 29, 1995  
69 days to decisionK954413 · Product code: **MDA** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k954413/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Elastomer, Silicone, For Scar Management (MDA)
Date received	Sep 21, 1995
Decision date	Nov 29, 1995
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Allied Biomedical Corp.</b>
Location	Paso Robles, CA, US
Contact	CATHY RIPPLE
510(k) history	9 submissions · 9 cleared · 1995-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954413/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 4, 2026